



RECEIVED

AUG 22 2001

TECH CENTER 1600/2900
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Havenga et al.

Serial No.: 09/348,354

Filed: July 7, 1999

For: CHIMAERIC ADENOVIRUSES

Examiner: G. Lee

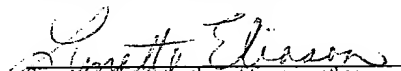
Group Art Unit: 1633

Attorney Docket No.: 4123US

CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail (under 37 C.F.R. § 1.8(a)) on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

January 24, 2001
Date of Deposit


Signature of registered practitioner or other person having reasonable basis to expect mailing to occur on date of deposit shown pursuant to 37 C.F.R. § 1.8(a)(1)(ii)

Lynette Eliason
Typed/printed name of person whose signature is contained above

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Second Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Second Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56 (b) exists.

DOCUMENTSU.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Issue Date</u>	<u>Inventor</u>
4,487,829	12/11/1984	Sharp et al.
4,517,686	05/21/1985	Ruoslahti et al.
4,578,079	03/25/1986	Ruoslahti et al.
4,589,881	05/20/1986	Pierschbacher et al.
4,593,002	06/03/1986	Dulbecco
4,792,525	12/20/1988	Ruoslahti et al.
4,797,368	01/10/1989	Carter et al.
4,956,281	09/11/1990	Wallner et al.
5,024,939	06/18/1991	Gorman
5,096,815	03/17/1992	Ladner et al.
5,166,320	11/24/1992	Wu et al.
5,198,346	03/30/1993	Ladner et al.
5,204,445	04/20/1993	Plow et al.
5,223,394	06/29/1993	Wallner
5,223,409	06/29/1993	Ladner et al.
5,240,846	08/31/1993	Collins et al.
5,246,921	09/21/1993	Reddy et al.
5,332,567	07/26/1994	Goldenberg
5,349,053	09/20/1994	Landolfi
5,403,484	04/04/1995	Ladner et al.
5,436,146	07/25/1995	Shenk et al.
5,443,953	08/22/1995	Hansen et al.
5,474,935	12/12/1995	Chatterjee et al.

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Issue Date</u>	<u>Inventor</u>
5,521,291	05/28/1996	Curiel et al.
5,534,423	07/09/1996	Palsson et al.
5,543,328	08/06/1996	McClelland et al.
5,547,932	08/20/1996	Curiel et al.
5,552,311	09/03/1996	Sorscher et al.
5,559,099	09/24/1996	Wickham et al.
5,571,698	11/05/1996	Ladner et al.
5,622,699	04/22/1997	Ruoslahti et al.
5,712,136	01/27/1998	Wickham et al.
5,731,190	03/24/1998	Wickham et al.
5,756,086	05/26/1998	McClelland et al.
5,770,442	06/23/1998	Wickham et al.
5,922,315	07/13/1999	Roy

Foreign Patent Documents

<u>Document No.</u>	<u>Date</u>	<u>Country</u>
259212	03/09/1988	EP
2078631	03/19/1990	JP
WO 91/00360	01/10/1991	PCT
WO 91/05805	05/02/1991	PCT
WO 91/05871	05/02/1991	PCT
WO 92/02553	02/20/1992	PCT
WO 92/13081	08/06/1992	PCT
WO 93/03769	03/04/1993	PCT
WO 93/06223	04/01/1993	PCT

Foreign Patent Documents

<u>Document No.</u>	<u>Date</u>	<u>Country</u>
WO 93/07282	04/15/1993	PCT
WO 93/07283	04/15/1993	PCT
WO 94/08026	04/14/1994	PCT
WO 94/10323	05/11/1994	PCT
WO 94/11506	05/26/1994	PCT
WO 94/15644	07/21/1994	PCT
WO 94/17832	08/14/1994	PCT
WO 94/24299	10/27/1994	PCT
WO 94/26915	11/24/1994	PCT
WO 95/05201	02/23/1995	PCT
WO 95/06745	03/09/1995	PCT
WO 95/14785	06/01/1995	PCT
WO 95/16037	06/15/1995	PCT
WO 95/21259	08/10/1995	PCT
WO 95/26412	10/05/1995	PCT
WO 95/27071	10/12/1995	PCT
WO 95/31187	11/23/1995	PCT
WO 95/31566	11/23/1995	PCT
WO 96/00790	01/11/1996	PCT
WO 96/07739	03/14/1996	PCT
WO 96/10087	04/04/1996	PCT
WO 96/13597	05/09/1996	PCT
WO 96/14837	05/23/1996	PCT
WO 96/17073	06/06/1996	PCT

Foreign Patent Documents

<u>Document No.</u>	<u>Date</u>	<u>Country</u>
WO 96/18740	06/20/1996	PCT
WO 97/24453	07/10/1997	PCT
WO 97/38723	10/23/1997	PCT
WO 98/07865	02/26/1998	PCT
WO 98/11221	03/19/1998	PCT
WO 98/13499	04/02/1998	PCT
WO 98/22609	05/28/1998	PCT
WO 98/32842	07/30/1998	PCT
WO 98/40509	09/17/1998	PCT

Other Documents

Albiges-Rizo et al., Human Adenovirus Serotype 3 Fiber Protein, Journal of Biological Chemistry, 266(6), 3961-3967 (1991).

Bai et al., Mutations That Alter an Arg-Gly-Asp (RGD) Sequence in the Adenovirus Type 2 Penton Base Protein Abolish Its Cell-Rounding Activity and Delay Virus Reproduction in Flat Cells, Journal of Virology, 67(9), 5198-5205 (1993).

Bailey et al., Phylogenetic Relationships among Adenovirus Serotypes, Virology, 205, 439-452 (1994).

Ball-Goodrich et al., Parvoviral Target Cell Specificity: Acquisition of Fibrotropism by a Mutant of the Lymphotropic Strain of Minute Virus of Mice Involves Multiple Amino Acid Substitutions within the Capsid, Virology, 184, 175-186 (1991).

Batra et al., Receptor-mediated gene delivery employing lectin-binding specificity, Gene Therapy, 1, 255-260 (1994).

Boursnell et al., In vitro construction of a recombinant adenovirus Ad2:Ad5, Gene, 13, 311-317 (1981).

- Caillet-Boudin et al., Functional and Structural Effects of an Ala to Val Mutation in the Adenovirus Serotype 2 Fibre, J. Mol. Biol., 217, 477-486 (1991).
- Chroboczek et al., The Sequence of the Genome of Adenovirus Type 5 and Its Comparison with the Genome of Adenovirus Type 2, Virology, 186, 280-285 (1992).
- Cotten et al., High-efficiency receptor-mediated delivery of small and large (48 kilobase gene constructs using the endosome-disruption activity of defective or chemically inactivated adenovirus particles, Proc. Natl. Acad. Sci. USA, 89, 6094-6098 (1992).
- Cotten et al., Transferrin-polycation-mediated introduction of DNA into human leukemic cells: Stimulation by agents that affect the survival of transfected DNA or modulate transferrin receptor levels, Proc. Natl. Acad. Sci. USA, 87, 4033-4037 (1990).
- Crawford-Miksza et al., Adenovirus Serotype Evolution Is Driven by Illegitimate Recombination in the Hypervariable Regions of the Hexon Protein, Virology, 224, 357-367 (1996).
- Crawford-Miksza et al., Analysis of 15 Adenovirus Hexon Proteins Reveals the Location and Structure of Seven Hypervariable Regions Containing Serotype-Specific Residues, J. Virol., 70(3), 1836-1844 (1996).
- Crompton et al., Expression of a foreign epitope on the surface of the adenovirus hexon, J. Gen. Virol., 75(1), 133-139 (1994).
- Crystal, Ronald G., Transfer of Genes to Humans: Early Lessons and Obstacles to Success, Science, 270, 404-410 (1995).
- Curiel et al., Adenovirus enhancement of transferrin-polylysine-mediated gene delivery, Proc. Natl. Acad. Sci. USA, 88, 8850-8854 (1991).
- Curiel et al., High-Efficiency Gene Transfer Mediated by Adenovirus Coupled to DNA-Polylysine Complexes, Human Gene Therapy, 3, 147-154 (1992).
- Defer et al., Human Adenovirus-Host Cell Interactions: Comparative Study with Members of Subgroups B and C, Journal of Virology, 64(8), 3661-3673 (1990).
- Dupuit et al., Regenerating Cells in Human Airway Surface Epithelium Represent Preferential Targets for Recombinant Adenovirus, Human Gene Therapy, 6, 1185-1193 (1995).
- Etienne-Julan et al., The efficiency of cell targeting by recombinant retroviruses depends on the nature of the receptor and the composition of the artificial cell-virus linker, Journal of General Virology, 73, 3251-3255 (1992).

- Falgout et al., Characterization of Adenovirus Particles Made by Deletion Mutants Lacking the Fiber Gene, Journal of Virology, 62(2), 622-625 (1988).
- Greber et al., Stepwise Dismantling of Adenovirus 2 during Entry into Cells, Cell, 75, 477-486 (1993).
- Green et al., Evidence for a repeating cross- β sheet structure in the adenovirus fibre, EMBO Journal, 2(8), 1357-1365 (1983).
- Grubb et al., Inefficient gene transfer by adenovirus vector to cystic fibrosis airway epithelia of mice and humans, Nature, 371, 802-806 (1994).
- Han et al., Ligand-directed retroviral targeting of human breast cancer cells, Proc. Natl. Acad. Sci. USA, 92, 9747-9751 (1995).
- Henry et al., Characterization of the Knob Domain of the Adenovirus Type 5 Fiber Protein Expressed in *Escherichia coli*, Journal of Virology, 68(8), 5239-5246 (1994).
- Hong et al., The Amino Terminus of the Adenovirus Fiber Protein Encodes the Nuclear Localization Signal, Virology, 185(2), 758-767 (1991).
- Horvath et al., Nonpermissivity of Human Peripheral Blood Lymphocytes to Adenovirus Type 2 Infection, Journal of Virology, 62(1), 341-345 (1988).
- Huang et al., Upregulation of Integrins $\alpha v \beta 3$ and $\alpha v \beta 5$ on Human Monocytes and T Lymphocytes Facilitates Adenovirus-Mediated Gene Delivery, Journal of Virology, 69(4), 2257-2263 (1995).
- Karayan et al., Oligomerization of Recombinant Penton Base of Adenovirus Type 2 and Its Assembly with Fiber in Baculovirus-Infected Cells, Virology, 202, 782-795 (1994).
- Kass-Eisler et al., Quantitative determination of adenovirus-mediated gene delivery to rat cardiac myocytes *in vitro* and *in vivo*, Proc. Natl. Acad. Sci. USA, 90, 11498-11502 (1993).
- Komoriya et al., The Minimal Essential Sequence for a Major Cell Type-specific Adhesion Site (CS1) within the Alternatively Spliced Type III Connecting Segment Domain of Fibronectin Is Leucine-Aspartic Acid-Valine, Journal of Biological Chemistry, 266(23), 15075-15079 (1991).
- Maraveyas et al., Targeted Immunotherapy – An update with special emphasis on ovarian cancer, Acta Oncologica, 32(7/8), 741-746 (1993).

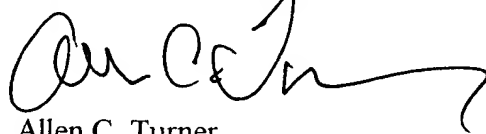
- Mastrangeli et al., In Vivo Gene Transfer to the Lung of Experimental Animals Using a Chimeric Ad5/Ad7 Adenovirus Vector, Ped. Pulm., Suppl., 12, 230, Abst. No. 180 (1995).
- Mastrangeli et al., "Sero-Switch" Adenovirus-Mediated In Vivo Gene Transfer: Circumvention of Anti-Adenovirus Humoral Immune Defenses Against Repeat Adenovirus Vector Administration by Changing the Adenovirus Serotype, Human Gene Therapy, 7, 79-87 (1996).
- Mathias et al., Multiple Adenovirus Serotypes Use α_v Integrins for Infection, Journal of Virology, 68(10), 6811-6814 (1994).
- Mautner et al., Recombination in Adenovirus: Analysis of Crossover Sites in Intertypic Overlap Recombinants, Virology, 139, 43-52, (1984).
- Mautner et al., Recombination in Adenovirus: DNA Sequence Analysis of Crossover Sites in Intertypic Recombinants, Virology, 131, 1-10 (1983).
- Michael et al., Addition of a short peptide ligand to the adenovirus fiber protein, Gene Therapy, 2, 660-668 (1995).
- Michael et al., Binding-incompetent Adenovirus Facilitates Molecular Conjugate-mediated Gene Transfer by the Receptor-mediated Endocytosis Pathway, Journal of Biological Chemistry, 268(10), 6866-6869 (1993).
- Miller et al., Targeted vectors for gene therapy, FASEB Journal, 9, 190-199 (1995).
- Neda et al., Chemical Modification of an Ecotropic Murine Leukemia Virus Results in Redirection of Its Target Cell Specificity, Journal of Biological Chemistry, 266(22), 14143-14146 (1991).
- Nemerow et al., Adenovirus entry into host cells: a role for α_v integrins, Trends In Cell Biology, 4, 52-55 (1994).
- Nemerow et al., The Role of α_v Integrins in Adenovirus Infection, Biology of Vitronectins and their Receptors, 177-184 (1993).
- Novelli et al., Deletion Analysis of Functional Domains in Baculovirus-Expressed Adenovirus Type 2 Fiber, Virology, 185, 365-376 (1991).
- Orkin et al., Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy, (1995), file:///F:/NIHrec.htm 1/4/01 1:37 pm.

- Peteranderl et al., Trimerization of the Heat Shock Transcription Factor by a Triple-Stranded α -Helical Coiled-Coil, Biochemistry, 31, 12272-12276 (1992).
- Pring-Åkerblom et al., Sequence Characterization and Comparison of Human Adenovirus Subgenus B and E Hexons, Virology, 212, 232-36 (1995).
- Roberts et al., Three-Dimensional Structure of the Adenovirus Major Coat Protein Hexon, Science, 232, 1148-51 (1986).
- Russell et al., Retroviral vectors displaying functional antibody fragments, Nucleic Acids Research, 21(5), 1081-1085 (1993).
- Signäs et al., Adenovirus 3 Fiber Polypeptide Gene: Implications for the Structure of the Fiber Protein, Journal of Virology, 53(2), 672-678 (1985).
- Silver et al., Interaction of Human Adenovirus Serotype 2 with Human Lymphoid Cells, Virology, 165, 377-387 (1988).
- Stewart et al., Difference imaging of adenovirus: bridging the resolution gap between X-ray crystallography and electron microscopy, EMBO Journal, 12(7), 2589-2599 (1993).
- Verma et al., Gene Therapy – promises, problems and prospects, Nature, 389, 239-42 (1997).
- Wadell, G., Molecular Epidemiology of Human Adenoviruses, Curr. Top. Microbiol. Immunol., 110, 191-220 (1984).
- Wagner et al., Coupling of adenovirus to transferrin–polylysine/DNA complexes greatly enhances receptor-mediated gene delivery and expression of transfected genes, Proc. Natl. Acad. Sci. USA, 89, 6099-6103 (1992).
- Watson et al., An Antigenic Analysis of the Adenovirus Type 2 Fibre Polypeptide, Journal of Virology, 69, 525-535 (1988).
- Wickham et al., Integrins $\alpha_v\beta_3$ and $\alpha_v\beta_5$ Promote Adenovirus Internalization but Not Virus Attachment, Cell, 73, 309-319 (1993).
- Wickham et al., Integrin $\alpha_v\beta_5$ Selectively Promotes Adenovirus Mediated Cell Membrane Permeabilization, Journal of Cell Biology, 127(1), 257-264 (1994).
- Chu et al., Cell targeting with retroviral vector particles containing antibody–envelope fusion proteins, Gene Therapy, 1, 292-299 (1994).

Applicants offer to supply any explanation or discussion of the documents which the Examiner feels is necessary or desirable and which is requested.

This Second Supplemental Information Disclosure Statement is filed after the mailing date of the first Office Action on the merits. I hereby certify that no item of information contained in the Second Supplemental Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the statement.

Respectfully submitted,



Allen C. Turner
Registration No. 33,041
Attorney for Applicants
TRASKBRITT
P. O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: (801) 532-1922

Date: January 24, 2001

ACT/jml

Enclosures: Form PTO-1449
Copy of documents cited

N:\2183\4123\IDS (2d supp).wpd